Anti-decubitus Mattress 250E

Users manual

CE

Manufacturer:
MOBILEX A/S
Grønlandsvej 5
DK-8660 Skanderborg
Denmark
www.mobilex.dk

1. General information

Dear customer,

This user manual contains a description of the medical device and important guidances to ensure a correct and safe usage of the product. It is important prior to use to read this manual carefully. It is especially important to read the safety requirements and follow these.
We continuously develop our products and we reserve the right without further notice to change the specifications and functions of products.

Intended use of the device
The Mobilex Product is medical device which is intended to be used only as an air support surface system for human body. It is suitable for pressure ulcer prevention and treatment. It has been specifically designed for prevention of bedsores and offers an affordable solution to 24-hour pressure area care. It can maximally be loaded with 100 kg.
Any other use is prohibited

Contraindications
Patient conditions for which the application of pressure relieving therapy on an alternation system is contraindicated are as follows: cervical or skeletal traction, unstable spinal cord injuries

By questions please take contact to your dealer or directly to Mobilex A/S.

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2. Safety requirements

General

- Make sure that this user manual is read by all persons using the device. Manufacturer doesn’t take any responsibility for damages and/or injuries, caused by the fact that the user manual has not been followed.
- Only use the product in flawless condition.
- If defects or errors are detected you must immediately contact the dealer.
- Follow the information on the product label.
- Only use the product for the described purpose.
- Avoid making constructive changes on the device, unless you have the manufacturer’s written acceptance for such modifications.
- The device must only be used on beds equipped with regular mattresses. It is forbidden to put the antidecubitus mattress directly on bed's frame.
- The device must not be loaded with more than 100 kg.
- The device is dedicated to be used indoors only
- A physical/occupational therapist should assist in first adjustment of the device for optimum support and correct functionality.

Electrical
To avoid incidents and to reduce the risk of burns, electrocution, fire, or injury to persons while using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

- Always unplug this product immediately after use.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquids.
- Do not reach for a product that has fallen into water. Unplug immediately. The device is not intended to be self-propelled while seated
- Close supervision is necessary when this product is used by, on, or near children or invalids.
- Use this product only for its intended use as described in this manual.
- Do not use attachments not recommended by the manufacturer.
- Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center

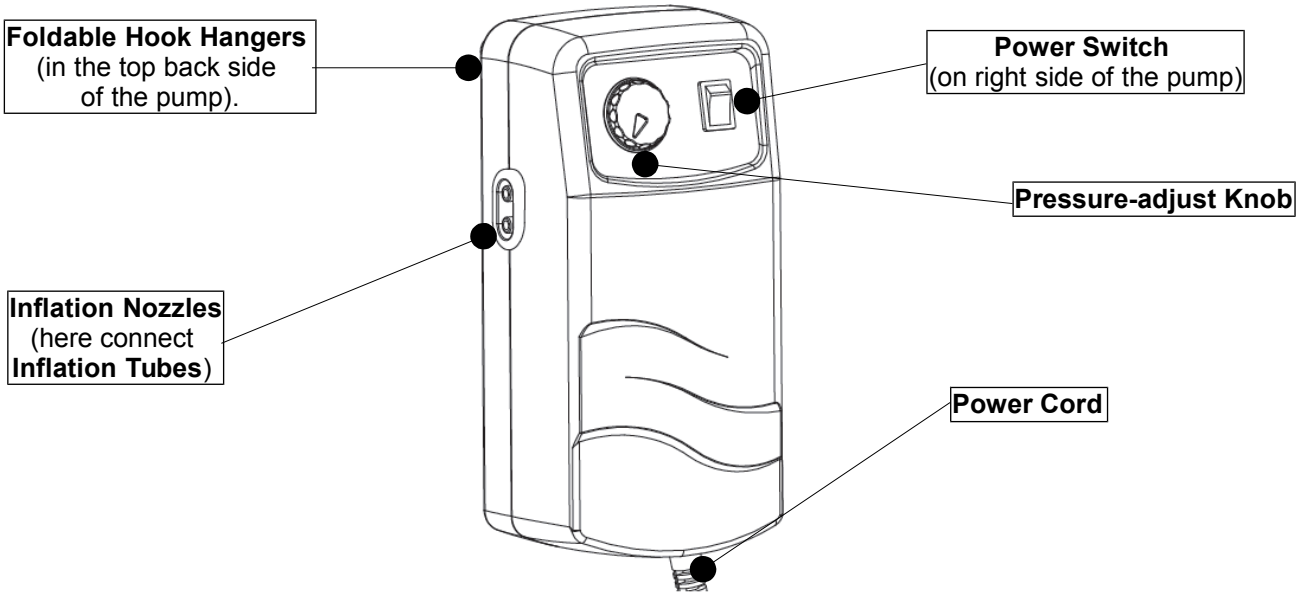
for examination and repair.
- Keep the cord away from heated surfaces.
- Never block the air openings of the product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
- Never drop or insert any object into any opening or hose.
- Do not use outdoors or operate where aerosol (spray) products are being used.
- Connect this product to a properly grounded outlet only. See Grounding Instructions.

Grounding
Before any connection is made, make certain that this product shall be connected to a protective earth conductor via the three-wire power cord; the three-blade plug shall be inserted only into a socket outlet that provides a protective earth contact.

3. Description

Product description
The device comes with all the necesary features for efficient decubitus prevention. It consists of fewseparate elements. No tools are required for assembly. Devices are supplied in carton boxes, detached in to few elements for easier transportation:

The contents are:
- 1 Pump
- 1 Mattress Pad
- 1 Set of Inflation Tubes
- 1 User manual



Q1 O2 OLA compressor

Assembly description
With looking on the picture above the device should be assembled in quite instinctive way. We recommend you to follow below steps:
- In the first place take all elements out of the box and check with the list from above if nothing is missing. If you'd discover at that stage that some part is missing or damaged, do not continue assembly process. Contact your supplier of the product right away.
- Lay the mattress pad on a foam base or other regular bed mattress. Do not put it directly on the bed frame! Please refer to the Specifications section for details.
- The inflation tubes should be towards the foot end so that they can be connected to the inflation nozzles on the pump.
- Cover it with a cotton sheet to avoid direct skin contact and reduce friction.
- Hang the pump over the frame or board at the foot end of the bed using the foldable hook hangers. Make sure the pump is secured.
- Connect the inflation tubes' ends to the mattress pad nozzles and to the pump's inflating

nozzles. Make sure the tubes are properly attached and that they sit tight on the nozzles.
- Make sure the inflation tubes are not kinked or tucked under the pad.
- Before inserting the plug into the outlet, make sure the voltage is compatible.
- Plug the power cord into an electrical outlet with grounded AC power. If the power cord has a grounding wire with a grounding pin, then this three-wire plug must be plugged properly into an outlet and grounded as shown in the figure in the “Grounding description” section.
- Make sure this product is well grounded.
- Make sure to disconnect the pump by unplugging the power cord when it is not in use.

Grounding description
This product should be grounded when it is equipped with a cord that contains a grounding wire with a grounding plug. In the event of an electrical short circuit, grounding reduces the risk of electric shock by providing an escape wire for the electric current.

Improper use of the grounding plug can result in a risk of electric shock.

Check with a qualified electrician or serviceman if the grounding instructions are not completely understood, or if in doubt as to whether the product is properly grounded.
If it is necessary to use an extension cord, use only a 3-wire extension cord that has a three-blade grounding plug and a 3-slot receptacle that will accept the plug on the product. Replace or repair if damaged.

Function description
- Turn on the power by pressing the power switch at the right side of the pump. The indicator of the power switch will come on. The pump starts to pump air into the mattress pad.
- For time-saving in the first inflation, turn the pressure knob to the full Firm / Hard position. It requires approximately 10 minutes for a bubble pad to be fully inflated.
- When mattress pad is fully inflated turn the pressure-adjust knob to set a comfortable pressure level from soft to firm according to patient’s weight and comfort.
- It is recommended that the pressure-adjust knob being turned to Firm when the bubble pad is firstly inflated. Users can then easily adjust the pressure level of the bubble pad to a desired firmness by themselves or according to the suggestion from a health care professional.
- If the pressure is consistently low, check for any leakage occurring in inflation tubes. Contact your local dealer for replacement of any damaged tubes.
- The deflating/inflating cycle runs automatically, when pump is turned on.

Transport recommendations
The device was not designed for frequent transportation. If it is necessary to transport it, we recommend to disassemble it in the way opposite to the assembly description from above. Device should packed in the way that it is stable and there is no risk of sudden and dangerous movements of the transported device.

Accessories
There are no accessories provided for this device

4. Technical data

Pump	Specification
Dimensions	23×11×8.1 cm (9.1x4.3x3.2 in)
Weight	1.1 kg (2.4 lbs)
Pressure Range	50 ~ 95 mmHg
Cycle Time	6 min/50Hz, 5 min/60Hz

Mattress Pad	Description	Dimensions	Material	Max. Load
250E	Bubble pad w/positioning extension	198×89×6.3 cm	PVC	100 kg

System	Specification
Classification	Class I; AP/APG NO*; Type BF**
Applied Part	Mattress Pad
Input Rating	AC 120V 60Hz or 100V 50/60Hz or 230V 50Hz 12W, 1A
Fuse Rating	250V, T1A
Air Output	4 Liter/min
Environment Requirements	• Temperature: Operation 50°F~95°F (10~35°C) Storage 5°F ~122°F (-15~50°C) Shipping 5°F ~158°F (-15~70°C) • Humidity: Operation 20%~80% non-condensing Storage 10%~90% non-condensing
Safety Standards	UL, c-UL, CE

Product label
The product label is located in the bottom of the frame

Sample of the product label only(not original)

5. Cleaning & Maintenance

Cleaning

In this section, we describe the procedures to clean and decontaminate the pump and bubble pad. It is important to follow these procedures before using the system on patients.
The cleaning task is required at least once a week to maintain personal hygiene.

Pump

- DO NOT immerse or soak the pump.
- Check for external damage and move the pump to a cleaning area.
- Place the pump on a work surface and spray or wipe the outside of the case with quaternary ammonium solution.
- DO NOT spray any cleaning solution directly on the surface of the pump.
- DO NOT use a Hypocarbonate or Phenolic based cleaning solution as this may cause damage to the case. Allow the solution to incubate for 10 minutes or accordingly as stated by the cleaning product used.
- Spray cloth with cleaning solution and clean faceplate. DO NOT allow excess cleaning solution on faceplate or control panel. (If solution gets inside, damage will occur.)
- Allow surface to thoroughly dry after cleaning.
- After the pump is thoroughly cleaned and dried, proceed to plug in the pump and test to see if it runs normally.

Bubble Pad

- Any obvious blood spots should be wet thoroughly with 1:9 Hypochiorite solution
- (1 part bleach to 9 parts water) and allow drying for at least 10 minutes. Then blot with a clean, damp cloth.
- Brush or wipe down all surfaces with soap and water before applying any liquid.
- Allow it to thoroughly air dry. Once the inside is dry, turn it back: wipe down the outside of the bag with disinfectant.
- Dry the bubble pad on a SUNLESS area after cleaning.

Maintanance

- Check the power cord and plug to see if there are abrasions or excessive wear.
- Plug in the pump and check the airflow from the hose connection port. The airflow should alternate between ports every half-cycle time.
- For storage lay the bubble pad flatly. Fold or roll it carefully. Unplug the pump and store with proper identification tag. Store device in dry places with non freezing temperatures.

6. Most common problems and solutions

Problems	Solutions
The pump doesn't work	1. Check if the plug is inserted firmly into the outlet. 2. Turn on the power switch again. 1. If the power indicator is ON and the pump still doesn't work, contact your local dealer immediately. 2. If the power indicator is OFF, there may be a faulty outlet. Try to connect the power cord to another outlet. If the power indicator is still OFF, contact a qualified electrician for main power check.
Incomplete inflation (Low pressure)	1. For a quick check, adjust the pressure to Firm. 2. Check to see if the inflation tubes connected to the pump are twisted or disconnected, or any leakage occurring. Always keep the tubes straight. Change the tubes if there is any leakage.

7. Disposal of the product

The product can not be disposed of with household waste but must be brought to the local recycling centre. Follow the national requirement to dispose the pump. It should be delivered to the deposit station for re-use or recycling.

8. Guarantee terms

Mobilex A/S offers guarantee by errors in production. It is: 2 years of warranty for pumps production defects & 1 year of warranty for mattress pads production defects.The guarantee is not valid by not-intended use of the product. Parts subject to normal wear are not covered by the guarantee, unless wear is caused by a manufacturing fault. In the event of damage, please notify your dealer. The guarantee does not cover transport cost. The guarantee does not cover injury or other damages eventually related to a malfunction of this product.

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9. Declaration of Conformity (CE)

The company Mobilex A/S, Grønlandsvej 5, 8660 Skanderborg, Denmark declares that the product

Anti-decubitus Mattress & Pump Set

Pump type: OLA Q1 O2 & Mattress type: 250E Item: 270011

is designed in accordance with the technical documentation and made of which conforms to the following basic requirements:

- **EU Council Directive 93/42/EEC for medical equipment Annex I of the June 14, 1993**

Lars Nygaard
Managing Director
Mobilex A/S

Skanderborg, the 2010-04-29 .....
signature